REMARKS

Initially, it is noted that the Examiner has indicated that claims 22-24 contain allowable subject matter. Applicant has rewritten dependent claim 22 as new independent claim 26. It is now believed that independent claim 26 is in proper form for allowance and such action is earnestly solicited.

Claims 23 and 24 depend from claim 26 and further define a microfluidic device not shown or suggested in the art. It is believed that claims 23-24 are allowable as depending from the allowable base claim and in view of the subject matter of each claim.

The Examiner has rejected claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Kriesel et al., United States Patent No. 6,416,495 in view of Kriesel et al., United States Patent No. 5,693,018. In addition, the Examiner has objected to claim 21 due to a lack of a period at the end of the claim. As hereinafter described, applicant has amended independent claim 21 to more particularly define the invention for which protection is sought. In addition, applicant has added new claims 27-28 to more fully define the invention for which protection is sought. Favorable consideration of claims 21-22 and 27-28 is respectfully sought in view of the following comments.

Claim 21 defines a microfluidic device for delivering a drug to an individual. The device includes a body defining a reservoir for receiving the drug and a chamber for receiving an aqueous solution therein. An output needle has an input in communication with the reservoir and an output receivable within the individual. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is received within the chamber. The hydrogel member is expandable in response to exposure to the aqueous solution. The hydrogel member is engageable with the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve defines a chamber and interconnects the reservoir and the output needle. The valve is movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle. As hereinafter described, nothing in either

of the cited references shows or suggests a microfluidic device for delivering drugs wherein a pressure source includes a hydrogel that expands in response to an aqueous solution.

The Kriesel et al. '495 patent discloses an implantable fluid delivery apparatus for infusing medical fluids into a patient. The apparatus includes a bolus delivery system including a magnetically responsive polymer gel which, upon being stimulated by an electromagnet, delivers precise bolus doses of medicinal fluids to a patient. It is noted that the apparatus disclosed in the '495 patent is implantable. Hence, it is contemplated for the polymer gel to be responsive to a singular external stimuli, e.g., magnetic stimulus or electromagnetic waves. This structure differs substantially from the microfluidic device defined in independent claim 21. More specifically, the hydrogel defined in claim 21 is responsive to an aqueous solution provided for in the chamber in which the hydrogel member resides. Nothing in the method in the '495 patent shows or suggests a structure wherein an aqueous solution actuates a hydrogel pressure source. Such a structure is entirely absent from the cited reference. Further, modifying the apparatus disclosed in the '495 patent to provide for a hydrogel pressure source that is responsive to a material or physical property originating within the device itself would require significant modification to the prior art devices, as well as, significant experimentation. As hereinafter described, the subdermal delivery device disclosed in the '018 patent cannot cure the deficiencies of the Kriesel et al. '495 patent.

The Kriesel et al. '018 patent is directed to a subdermal delivery device that includes a needle and an adhesive for affixing the device to an individual. Nothing in the '018 patent shows or suggests a hydrogel pressure source responsive to a predetermined parameter of an aqueous solution. Further, the apparatus disclosed in the '018 patent is directed to a non-implantable device, unlike the apparatus disclosed in the '495 patent. Hence, there is no teaching or suggestion in the cited references for the combination suggested by the Examiner. As such, it is believed that independent claim 21 now defines over the cited references and is in proper form for allowance.

Claim 27 defines a microfluidic device for delivering a drug to an individual. The microfluidic device includes a body defining a reservoir for receiving the drug and an output needle having an input in communication with the reservoir and an output receivable within the individual. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is expandable in response to exposure to a predetermined physical property originating within the body. The hydrogel member engages the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve defines a chamber and interconnects the reservoir and the output needle. The valve is movable between a non-actuated position when the valve prevents the flow of drug from the reservoir to the output needle and an actuated position when the valve allows for the flow of the drug to the reservoir to the output needle. As hereinafter described, nothing in either of the cited references shows or suggests a microfluidic device for delivering a drug to an individual wherein a hydrogel pressure source is responsive to exposure to a predetermined physical property originating within the body of the microfluidic device.

As heretofore described with respect to the independent claim 21, the hydrogel member in the '495 patent is responsive to stimuli delivered externally of a body since the apparatus disclosed therein is implantable. More specifically, the hydrogel disclosed in the '495 patent is responsive to temperature, magnetic stimuli or electro-magnetic stimuli originating outside of the patient in which the apparatus is implanted. This structure differs substantially from the microfluidic device of independent claim 21 wherein the predetermined physical property to which the hydrogel member responds originates within the body of the microfluidic device. Nothing in either of the cited reference shows or suggests a microfluidic device incorporating a hydrogel pressure source that is responsive to a predetermined physical property that originates within the body of such device. Consequently, it is believed that independent claim 27 defines over the cited references and is in proper form for allowance.

Claim 28 depends from claim 27 and further defines a microfluidic device not shown or suggested in the cited references. More specifically, claim 28 specifies that the predetermined physical properties are defined by an aqueous solution which originates within the body. Again, such a structure is not disclosed in the cited references. As such, it is believed that claim 28 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

In view of the foregoing, applicant believes that the present application with claims 21, 23-24 and 26-27 is in proper form for allowance and such action is earnestly solicited. The Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

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